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Application of:	Oshlack et al.	Confirmation No.:	7929
Serial No.:	10/809,766	Art Unit:	1617
Filed:	March 24, 2004	Examiner:	Edward J. Webman
For:	CONTROLLED RELEASE OXYCODONE COMPOSITIONS	Attorney Docket No.:	305158-999274 (6750-276-999)

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

Enclosure accompanying this Information Disclosure Statement is a List of References Cited by Applicants (References **A01-A119**; **B01-B78**; and **C01-C256**).

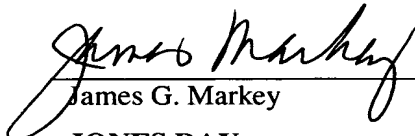
This application is a continuation application under 37 C.F.R. §1.53(b) or (d). Copies of the above references were submitted by Applicants and/or cited by the Examiner in prior Application Nos. 10/706,496, filed November 12, 2003; 10/163,484, filed June 5, 2002; 09/933,411, filed August 20, 2001; 09/784,888, filed February 16, 2001; 09/481,909, filed January 12, 2000; 08/909,328, filed August 11, 1997; 08/618,344, filed March 19, 1996, now Patent No. 5,656,295; 08/081,302, filed June 18, 1993, now Patent No. 5,549,912; and 07/800,549, filed November 21, 1991, now Patent No. 5,266,331, to all of which this application claims priority under 35 U.S.C. §120. Hence, copies of the List of References Cited by Applicants in this Information Disclosure Statement are not being submitted pursuant to 37 C.F.R. §1.98(d). However, should the Examiner request copies of the references, Applicants would be happy to provide them.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R §1.97(b), but before the mailing date of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the \$180.00 fee set forth in 37 C.F.R. §1.17(p) and any other fees that may be due in connection with this filing to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed.

No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made. 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: April 14, 2005

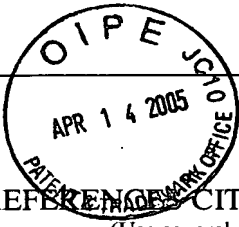

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Enclosures



LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

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APPLICANT
Oshlack et al.

FILING DATE
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GROUP
1617

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	2,738,303	03/13/1956	Blythe			
	A02	2,921,883	01/19/1960	Reese et al.			
	A03	3,082,154	03/19/1963	Allan			
	A04	3,458,622	07/29/1969	Hill			
	A05	3,492,397	01/27/1970	Peters et al.			
	A06	3,634,584	01/11/1972	Poole			
	A07	3,773,920	11/20/1973	Nakamoto et al.			
	A08	3,845,770	11/05/1974	Theeuwes et al.			
	A09	3,870,790	03/11/1975	Lowey et al.			
	A10	3,916,899	11/04/1975	Theeuwes et al.			
	A11	3,965,256	06/22/1976	Leslie			
	A12	3,922,339	11/25/1975	Shear			
	A13	4,063,064	12/13/1977	Saunders et al.			
	A14	4,088,864	05/09/1978	Theeuwes et al.			
	A15	4,132,753	01/02/1979	Blichare al.			
	A16	4,235,870	11/15/1980	Leslie			
	A17	4,259,314	03/31/1981	Lowey			
	A18	4,351,825	09/28/1982	Sothmann et al.			
	A19	4,369,172	01/18/1983	Schor et al.			
	A20	4,377,568	03/22/1983	Chopra			
	A21	4,385,078	05/24/1983	Onda et al.			
	A22	4,389,393	06/21/1983	Schor et al.			
	A23	4,421,736	12/20/1983	Walters			
	A24	4,438,091	03/24/1984	Gruber et al.			
	A25	4,443,428	04/17/1984	Oshlack et al.			
	A26	4,464,378	08/07/1984	Hussain			
	A27	4,483,847	11/20/1984	Augart			
	A28	4,520,172	05/28/1985	Lehmann et al.			
	A29	4,547,359	10/15/1985	Zierenberg et al.			
	A30	4,548,990	10/22/1985	Mueller et al.			
	A31	4,557,925	12/10/1985	Lindahl et al.			
	A32	4,600,645	07/15/1986	Ghebre-Sellassie et al.			
	A33	4,609,542	09/02/1986	Pano et al.			
	A34	4,708,874	11/24/1987	De Haan et al.			
	A35	4,722,815	02/02/1988	Shibanai			

	A36	4,728,513	03/01/1988	Ventouras			
	A37	4,797,410	01/10/1989	El-Fakahany			
	A38	4,806,337	02/21/1989	Snipes et al.			
	A39	4,828,836	05/09/1989	Elger et al.			
	A40	4,834,984	05/30/1989	Goldie et al.			
	A41	4,834,985	05/30/1989	Elger et al.			
	A42	4,844,907	07/04/1989	Elger et al.			
	A43	4,844,909	07/04/1989	Goldie et al.			
	A44	4,861,598	08/29/1989	Oshlack			
	A45	4,894,234	01/16/1990	Sharma et al.			
	A46	4,935,246	06/19/1990	Ahrens			
	A47	4,970,075	11/13/1990	Oshlack			
	A48	4,983,730	01/08/1991	Domeshek et al.			
	A49	4,990,341	02/05/1991	Goldie et al.			
	A50	5,007,790	04/16/1991	Shell			
	A51	5,019,397	05/28/1991	Wong et al.			
	A52	5,023,089	06/11/1991	Sakamoto et al.			
	A53	5,024,842	06/18/1991	Edgren et al.			
	A54	5,026,560	06/25/1991	Makino et al.			
	A55	5,030,400	07/09/1991	Danielsen et al.			
	A56	5,068,110	11/26/1991	Fawzi et al.			
	A57	5,071,646	12/10/1991	Malkowska et al.			
	A58	5,098,718	03/24/1992	Ardaillon et al.			
	A59	5,122,384	06/16/1992	Paradissis et al.			
	A60	5,126,145	06/30/1992	Evanstad et al.			
	A61	5,132,142	07/21/1992	Jones et al.			
	A62	5,133,974	07/28/1992	Paradissis et al.			
	A63	5,167,964	12/01/1992	Muhammed et al.			
	A64	5,169,645	12/08/1992	Shukla et al.			
	A65	5,178,868	01/12/1993	Malmqvist et al.			
	A66	5,196,203	03/23/1993	Boehm			
	A67	5,202,128	04/13/1993	Morella et al.			
	A68	5,206,030	04/27/1993	Wheatley et al.			
	A69	5,215,758	06/01/1993	Krishnamurthy			
	A70	5,219,575	06/15/1993	Von Bommel et al.			
	A71	5,248,516	09/28/1993	Wheatley et al.			
	A72	5,258,436	11/02/1993	Wheatley et al.			
	A73	5,266,311	11/30/1993	Cerretti et al.			
	A74	5,266,331	11/30/1993	Oshlack et al.			
	A75	5,273,760	12/28/1993	Oshlack et al.			
	A76	5,283,065	02/01/1994	Doyon et al.			
	A77	5,286,493	02/15/1994	Oshlack et al.			
	A78	5,292,461	03/08/1994	Juch et al.			
	A79	5,321,012	06/14/1994	Mayer et al.			
	A80	5,330,766	07/19/1994	Morella et al.			

	A81	5,356,467	10/18/1994	Oshlack et al.			
	A82	5,378,474	01/03/1995	Morella et al.			
	A83	5,384,130	01/04/1995	Kamada			
	A84	5,411,745	05/02/1995	Oshlack et al.			
	A85	5,456,923	10/10/1995	Nakamichi et al.			
	A86	5,460,826	10/24/1995	Merrill et al.			
	A87	5,472,712	12/05/1995	Oshlack et al.			
	A88	5,478,577	12/26/1995	Sackler et al.			
	A89	5,500,227	03/19/1996	Oshlack et al.			
	A90	5,502,058	03/26/1996	Mayer et al.			
	A91	5,508,042	04/16/1996	Oshlack et al.			
	A92	5,508,403	04/16/1996	Akiyama et al.			
	A93	5,520,931	05/28/1996	Persson et al.			
	A94	5,549,912	08/27/1996	Oshlack et al.			
	A95	5,580,578	12/03/1996	Oshlack et al.			
	A96	5,593,695	01/14/1997	Merril et al.			
	A97	5,601,842	02/11/1997	Bartholomaeus			
	A98	5,614,218	03/25/1997	Olsson			
	A99	5,629,011	05/13/1997	Illum			
	A100	5,637,320	06/10/1997	Bourke et al.			
	A101	5,656,295	08/12/1997	Oshlack et al.			
	A102	5,667,805	09/16/1997	Merrill et al.			
	A103	5,670,172	09/23/1997	Buxton et al.			
	A104	5,672,360	09/30/1997	Sackler et al.			
	A105	5,681,585	10/28/1997	Oshlack et al.			
	A106	5,811,126	09/22/1998	Krishnamurthy			
	A107	5,843,480	12/01/1998	Miller et al.			
	A108	5,849,240	12/15/1998	Miller et al.			
	A109	5,879,705	03/09/1999	Heafield et al.			
	A110	5,891,471	04/06/1999	Miller et al.			
	A111	5,958,452	09/28/1999	Oshlack et al.			
	A112	5,958,459	09/28/1999	Chasin et al.			
	A113	5,965,163	10/12/1999	Miller et al.			
	A114	5,968,551	10/19/1999	Oshlack et al.			
	A115	6,103,261	08/15/2000	Chasin et al.			
	A116	6,143,322	11/07/2000	Sackler et al.			
	A117	6,261,599 B1	07/17/2001	Oshlack et al.			
	A118	6,294,195 B1	09/25/2001	Oshlack et al.			
	A119	6,419,960 B1	07/16/2002	Krishnamurthy et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	CA 635,283	06/23/82	Canada				
	B02	CA 1,296,633	03/03/92	Canada				

	B03	CA 1,297,025	03/10/92	Canada				
	B04	CA 2082573	11/10/92	Canada				
	B05	CA 2131350 (A1)	01/94	Canada				
	B06	9047732	07/12/90	Australia				
	B07	9341654	02/16/95	Australia				
	B08	0097523 (A2)	06/21/83	EPO				
	B09	0097523 (A3)	06/21/83	EPO				
	B10	0097523 (B1)	06/21/83	EPO				
	B11	0108218 (A2)	05/16/84	EPO				
	B12	0147780 (A2)	07/10/85	EPO				
	B13	0235986 (A1)	09/09/87	EPO				
	B14	0235986 (B1)	02/12/87	EPO				
	B15	0235986 (B2)	02/12/87	EPO				
	B16	0249347	12/16/1987	EPO				
	B17	0253104 (A1)	01/20/88	EPO				
	B18	0253104 (B1)	05/22/87	EPO				
	B19	0267702 (A3)	05/18/88	EPO				
	B20	0271193 (A2)	10/22/87	EPO				
	B21	0271193 (A3)	10/22/87	EPO				
	B22	0271193 (B1)	06/88	EPO				
	B23	0327295 (A2)	08/09/89	EPO				
	B24	0361680 (B1)	07/13/94	EPO				
	B25	0361910 (A1)	04/04/90	EPO				
	B26	0377517 (A2)	07/11/90	EPO				
	B27	0377518 (A2)	01/05/90	EPO				
	B28	0377518 (A3)	01/05/90	EPO				
	B29	0377518 (B1)	07/11/90	EPO				
	B30	0388954 (A2)	03/22/90	EPO				
	B31	0388954 (A3)	03/22/90	EPO				
	B32	0388954 (B1)	03/22/90	EPO				
	B33	0415693 (A1)	03/06/91	EPO				
	B34	0430287 (B1)	10/12/94	EPO				
	B35	0452145 (A2)	10/16/91	EPO				
	B36	0532348 (A2)	03/17/93	EPO				
	B37	0532348 (A3)	09/11/92	EPO				
	B38	0532348 (B1)	09/11/92	EPO				
	B39	0533297 (A1)	03/24/93	EPO				
	B40	0534628 (A1)	03/21/93	EPO				
	B41	0534628 (B1)	04/09/92	EPO				
	B42	0535841 (A1)	04/07/93	EPO				
	B43	0546676 (A1)	06/16/93	EPO				
	B44	0548448 (A1)	06/30/93	EPO				
	B45	0553392 (A1)	08/04/93	EPO				
	B46	0576643	11/25/92	EPO				
	B47	0580860 (A1)	02/02/94	EPO				
	B48	0609961 (A1)	08/10/94	EPO				

B49	0636370 (A1)	02/01/95	EPO				
B50	0636370 (B1)	06/09/94	EPO				
B51	0665010 (A1)	08/02/95	EPO				
B52	1258246 (A2)	11/20/02	EPO				
B53	DE 32 46 492	06/30/1983	Germany			X	
B54	2053681 (B)	04/04/84	Great Britain				
B55	2178313 (A)	02/11/87	Great Britain				
B56	2196848	05/11/88	Great Britain				
B57	04081086	04/02/92	Japan				
B58	80/00659	09/26/79	PCT				
B59	92/01446	02/06/92	PCT				
B60	92/02209 (A1)	02/20/92	PCT				
B61	92/06679	04/30/92	PCT				
B62	92/08459	05/29/92	PCT				
B63	93/04675	03/18/93	PCT				
B64	93/07859 (A1)	04/29/93	PCT				
B65	93/07861	04/29/93	PCT				
B66	93/10765	06/93	PCT				
B67	93/18753	09/30/93	PCT				
B68	94/03160	02/17/94	PCT				
B69	94/03161	02/94	PCT				
B70	94/05262	03/17/94	PCT				
B71	94/22431	10/13/94	PCT				
B72	96/00066	01/04/96	PCT				
B73	96/01629	01/25/96	PCT				
B74	96/14058	05/27/96	PCT				
B75	01/08661 (A2)	07/27/00	PCT				
B76	02/100382 A2	12/19/02	PCT				
B77	03/004030 A1	01/16/03	PCT				
B78	2170104	07/30/86	United Kingdom				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Abstract of Japan, XP-002241447, May 12, 1988.
C02	Abstracts from the Twelfth Annual Congress of the Oncology Nursing Society, May 1987.
C03	Advertisement: MS Contin 1986, 1987 The Purdue Frederick Company.
C04	Advertisement: Roxanol SR., 1985 Roxane Labs, Inc.
C05	Agabeyoglu et al. Studies on Sustained Release II: In Vivo Performance of the Inert Matrix Sulfamethiozole Tablet, Employing Polymethylmethacrylate. 1986;12(3) DRUG DEVELOPMENT & INDUSTRIAL PHARMACY 423-430.
C06	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1987; (7 th ed.):3-172.
C07	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1988; (8 th ed.):3-179.
C08	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1989; (9 th ed.):3-199.
C09	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1990; (10 th ed.):3-200.
C10	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1991; (11 th ed.):3-200.

C11	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1992; (12 th ed.):3-197.
C12	Approved drug products with therapeutic equivalence evaluations. U.S. Dept. of Health and Human Services. 1993; (13 th ed.):3-198.
C13	April 11, 2004 Amicus Curae Brief of Guilford Pharmaceuticals in Support of Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company and EuroCeltique S.A. in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs/Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaimant-Appellee), Endo Pharmaceuticals Holdings Inc. (Defendant-Appellee)</i> , United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226.
C14	April 2, 2004 Corrected Brief of Plaintiffs-Appellants in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs/Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaimant-Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant)</i> , United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226.
C15	Arkininstall et al. Efficacy of controlled-release codeine in chronic non-malignant pain: a randomized, placebo-controlled clinical trial. <i>Pain</i> . 1995 Aug;62(2):169-78.
C16	August 3, 2001 Paragraph 1V Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Teva Pharmaceuticals USA to Euro-Celtique S.A.
C17	Balant et al. CONTROLLED RELEASE PRODUCTS: THERAPEUTIC AND BIOPHARMACEUTIC ASSESSMENT, <i>Ch. II Controlled Release Products – Pharmacokinetic Aspects</i> , Gundert-Remy, U. and Möller, H., eds., Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart. 1990;21-37.
C18	Bannerjee et al. Novel drug delivery systems. An overview of their impact on clinical pharmacokinetic studies. <i>Clin Pharmacokinet</i> . 1991 Jan;20(1):1-14.
C19	Beaver et al. <i>Analgesic Studies of Codeine and Oxycodone in Patients with Cancer. I. Comparisons of Oral with Intramuscular Codeine and of Oral with Intramuscular Oxycodone</i> , 207 <i>J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS</i> 92-100 (1978).
C20	Beaver et al. <i>Analgesic Studies of Codeine and Oxycodone in Patients with Cancer. II. Comparisons of Intramuscular Oxycodone with Intramuscular Morphine and Codeine</i> , 207 <i>J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS</i> . 1978;101-108.
C21	Beckett. <i>Rate Control in Drug Therapy</i> , Ch. 17: Once daily rate-controlled drug therapy, Prescott, L.F. and Nimmo, W.S. eds., Churchill Livingstone, Edinburgh. 1985;166-179.
C22	Benziger et al. A pharmacokinetic/pharmacodynamic study of controlled-release oxycodone. <i>J Pain Symptom Manage</i> . 1997 Feb;13(2):75-82.
C23	Beubler. <i>Medikamentöse Schmerztherapie: Kriterien, Möglichkeiten, Risiken</i> . <i>Therapiewoche Österreich</i> . 1992;7(2):1-15. English translation.
C24	Black. A rational approach to cancer pain management. <i>J. of Family Practice</i> . 1989;28(3):267-8.
C25	Bloomfield et al. Analgesic efficacy and potency of two oral controlled-release morphine preparations. <i>Clin Pharmacol Ther</i> . 1993 Apr;53(4):469-78.
C26	Bobs et al. Steady-State Pharmacokinetics of Sustained Release Morphine Tablets (MS Contin) and Morphine Sulfate Solution (MSS). 6 <i>Proceedings of ASCO</i> . 1987;44(Abtract #171).
C27	Bourget et al. Study of the bioequivalence of two controlled-release formulations of morphine. <i>Int J Clin Pharmacol Ther</i> . 1995 Nov;33(11):588-94.
C28	Brooks et al. Principles of Cancer Pain Management: Use of Long-acting Oral Morphine, 28(3) <i>J. FAMILY PRACTICE</i> . 1989;275-280.
C29	Brooks et al. Use of Continuous Release Morphine Sulfate (CRMS) in Cancer Patients (pts) with Chronic Pain. 5 <i>Proceedings of ASCO</i> . 1986;251(Abtract #980).
C30	Brooks et al. Use of Continuous Release Morphine Sulfate (CRMS) in Cancer Patients with Chronic Pain. 6 <i>Proceedings of ASCO</i> . 1987;264(Abtract #1037).
C31	Bruera et al. A randomized, double-blind, double-dummy, crossover trial comparing the safety and efficacy of oral sustained-release hydromorphone with immediate-release hydromorphone in patients with cancer pain. <i>Canadian Palliative Care Clinical Trials Group</i> . <i>J Clin Oncol</i> . 1996 May;14(5):1713-7.
C32	Bruera et al. Randomized, double-blind, cross-over trial comparing safety and efficacy of oral controlled-release oxycodone with controlled-release morphine in patients with cancer pain. <i>J Clin Oncol</i> . 1998 Oct;16(10):3222-9.
C33	Chang et al. Sustained drug release from tablets and particles through coating.
C34	Chary et al. The dose-response relationship of controlled-release codeine (Codeine Contin) in chronic cancer pain. <i>J Pain Symptom Manage</i> . 1994 Aug;9(6):363-71.
C35	Chmielewski et al. Comparative bioavailability of multiple doses of sustained release morphine tablets (Roxanol SR q 12h) and immediate release morphine solution (q 4h), 6 <i>Proceedings of ASCO</i> . 1987;275(Abtract #1080).
C36	Citron et al. Long-term administration of controlled-release oxycodone tablets for the treatment of cancer pain. <i>Cancer Investigation</i> . 1998;16(8):562-571.
C37	Codeine. Available at http://esc.syrres.com/interkow/webprop.exe .
C38	Codeine. Clark's Isolation and Identification of Drugs. 1986;490-1.
C39	Codeine. The Merck Index 1989;(11 th ed.):384-5.

C40	Comerford. Efficacy of controlled-release oxycodone. J Clin Oncol. 1999 Feb;17(2):738.
C41	Conrad et al. Sustained drug release from tablets and particles through coating in Pharmaceutical Dosage Forms-Tablets (Lieberman et al., eds). 1982. 3(4):149-221.
C42	Conrad et al., Sustained drug release from tablets and particles through coating in Pharmaceutical Dosage Forms-Tablets (Lieberman et al., eds). 1982. 3(4):149-221.
C43	Cowan et al. Two assays for dihydrocodeine in plasma and in urine and their use to determine the bioavailability of a controlled-release product. J Pharm Sci. 1988 Jul;77(7):606-9.
C44	Cundiff et al. Evaluation of a cancer pain model for the testing of long-acting analgesics. The effect of MS Contin in a double-blind, randomized crossover design. Cancer. 1989 Jun 1;63(11 Suppl):2355-9.
C45	Curtis et al. Relative potency of controlled-release oxycodone and controlled-release morphine in a postoperative pain model. Eur J Clin Pharmacol. 1999 Aug;55(6):425-9.
C46	Deschamps et al. The evaluation of analgesic effects in cancer patients as exemplified by a double-blind, crossover study of immediate-release versus controlled-release morphine. J Pain Symptom Manage. 1992 Oct;7(7):384-92.
C47	Dhaliwal et al. Randomized evaluation of controlled-release codeine and placebo in chronic cancer pain. J Pain Symptom Manage. 1995 Nov;10(8):612-23.
C48	DiPersio et al. Predicting plasma procainamide concentrations resulting from a sustained-release preparation. Clin Pharm. 1985 Mar-Apr;4(2):186-91.
C49	Endo's Initial Post-Trial Brief dated 7/25/2003 in Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C50	Endo's Post-Trial Proposed Findings of Fact dated 7/25/2003 in Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C51	Endo's Post-Trial Proposed Conclusions of Law dated 7/25/2003 in Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C52	Endo's Post-Trial Response Brief dated 8/8/2003 in Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A., 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C53	Endo's February 17, 2004 Memorandum in support of its Motion for Relief from Order with respect to Infringement in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)</i> Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS).
C54	Endo's March 19, 2004 Reply Memorandum in support of its Motion for Relief from Order with respect to Infringement in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)</i> Civil Action Nos. 00-CV 8029 (SHS); 01-CV 2109 (SHS) and 01-CV 8177(SHS).
C55	Endo's Post-Trial Proposed Conclusions Of Law in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings, Inc. (Defendant) v. EuroCeltique S.A.(Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS).
C56	Endo's Post-Trial Proposed Findings of Fact in <i>Purdue Pharma L.P., The Purdue Frederick Company, the P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings. Inc. (Defendant) v. EuroCeltique S.A. (Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS)
C57	Esterhail et al. Post operative analgesic efficacy of controlled release morphine. Pain. 1987;(Suppl.4):Abstract S230.
C58	February 25, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Impax Laboratories, Inc. to Purdue Pharma LP. and The Purdue Frederick Company.
C59	February 25, 2003 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10, 20 and 40 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P., The P.F. Laboratories, Inc. and Euro-Celtique S.A.
C60	February 9, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company, and The P.F. Laboratories, Inc.
C61	Federal Court of Appeals Decision, <i>Purdue Pharma, L.P., v. Boehringer Ingelheim GmbH</i> , Docket No. 00-1398, Judge Sidney Stein; decided February 1, 2001.
C62	Federal District Court Decision, <i>Purdue Pharma, LP., v. Boehringer Ingelheim GmbH</i> , 98 F. Supp. 2d. 362; 2000, U.S. Dist., S.D.N.Y.; U.S.P.Q. 2D 1168, Judge Sidney Stein; decided May 16, 2000.
C63	Finn et al. Crossover Study of Sustained Release Morphine Sulfate (Roxanol SR) in Advanced Cancer, 6 Proceedings of ASCO 44. 1987;Abstract #1027.
C64	Finn et al. Placebo-blinded study of morphine sulfate sustained-release tablets and immediate-release morphine sulfate solution in outpatients with chronic pain due to advanced cancer. J Clin Oncol. 1993 May;11(5):967-72.
C65	Fitzmartin et al. Stigma associated with opioid therapy for pain, results of a health care provider survey, AMERICAN PAIN SOCIETY, 14 TH annual Scientific Meeting, 1995 Nov. 9-12;A144 abstract # 95877.

C66	Flanders et al. The Control of Drug Release From Conventional Melt Granulation Matrices. Drug Development and Industrial Pharmacy. 1987;13(6):1001-22.
C67	Foldes. Role of oral and parenteral drugs in the management of intractable pain. Pain. 1988;9:286-9.
C68	Foley. The treatment of cancer pain. N Engl J Med. 1985 Jul 11;313(2):84-95.
C69	Gibaldi et al. PHARMACOKINETICS, 2 nd Ed., Rev. & Exp. Marcel Dekker, Inc., New York. 1982;456-457;353-357.
C70	Gibaldi et al. PHARMACOKINETICS, Ch. 4: Absorption Kinetics and Bioavailability, 2 nd Ed., Rev. & Exp., Marcel Dekker Inc., New York. 1985;145-198.
C71	Gibaldi. Prolonged-release medication. Biopharm. and Clin. Pharmacokinetics. 4 th ed.1991;124-45.
C72	Gibaldi. Prolonged-release medication. Biopharmaceutics and Clinical Pharmacokinetics. 1984 (3 rd ed);27:113-130.
C73	Glare et al. Oxycodone – a substitute for morphine in cancer pain management? PALLIATIVE MEDICINE. 1992; 6:79-80.
C74	Gostick et al. <i>A comparison of the efficacy and adverse effects of controlled release dihydrocodeine and immediate release dihydrocodeine in the treatment of pain in osteoarthritis and chronic back pain</i> , The Edinburgh Symposium on Pain Control and Medical Education (R.G. Twycross, ed.), Royal Society of Medicine Services International Congress and Symposium Series No. 149, London. 1989;137-143.
C75	Gourlay et al. Influence of a high-fat meal on the absorption of morphine from oral solutions. Clin Pharmacol Ther. 1989 Oct;46(4):463-8.
C76	Gourlay et al. The reproducibility of bioavailability of oral morphine from solution under fed and fasted conditions. J Pain Symptom Manage. 1991 Oct;6(7):431-6.
C77	Grandy et al. Bioavailability comparison of three controlled-release codeine formulations vs. conventional oral codeine. J. Pain & Symptom Manage. 1988; 3(3):Abstract S17 #27.
C78	Grass et al. Sustained and controlled-release drug delivery systems. Modern Pharmaceutics, Ch. 16: 2 nd Ed., Marcel Dekker, Inc., New York. 1989;635-671.
C79	Guay et al. Pharmacokinetics of codeine after single- and multiple-oral-dose administration to normal volunteers. J Clin Pharmacol. 1987 Dec;27(12):983-7.
C80	Hagen et al. Comparative clinical efficacy and safety of a novel controlled-release oxycodone formulation and controlled-release hydromorphone in the treatment of cancer pain. Cancer. 1997 Apr 1;79(7):1428-37.
C81	Hale et al. Efficacy and safety of controlled-release versus immediate-release oxycodone: randomized, double-blind evaluation in patients with chronic back pain. Clin J Pain. 1999 Sep;15(3):179-83.
C82	Hanks. Controlled-release morphine (MST Contin) in advanced cancer. The European experience. Cancer. 1989 Jun 1;63(11 Suppl):2378-82.
C83	Hays et al. Comparative clinical efficacy and safety of immediate release and controlled release hydromorphone for chronic severe cancer pain. Cancer. 1994 Sep 15;74(6):1808-16.
C84	Heinrich-Nols et al. Bioequivalence study of two morphine extended release formulations after multiple dosing in healthy volunteers. Int J Clin Pharmacol Ther. 1999 Mar;37(3):153-8.
C85	Heiskanen et al. Controlled-Release Oxycodone and Morphine in Cancer Related Pain. Pain. 1997; 73:37-45.
C86	Heiskanen et al. Morphine or Oxycodone in Cancer Pain?, Acta Oncologica. 2000; 39(8) 941-7.
C87	Hood et al. Dose and Effectiveness of Oral Oxycodone Following PCA Morphine For Post-Operative Analgesia, Abstracts 7 th World Congress on Pain. 1993,390(Abstract 1028, Poster #14).
C88	Houde et al. ANALGETICS, Ch. III: Clinical Measurement of Pain, deStevens, G. ed., Academic Press, New York. 1965;75-122.
C89	Houde. The Use and Misuse of Narcotics in the Treatment of Chronic Pain. ADVANCES IN NEUROLOGY. 1974;4:527-536.
C90	Houston et al. The influence of food on the pharmacokinetics of morphine from two controlled release preparations. British J. Clinical Res. 1991;2 201-9.
C91	Hunt et al. Comparison of the pharmacokinetic profiles of two oral controlled-release morphine formulations in healthy young adults. Clin Ther. 1991 Jul-Aug;13(4):482-8.
C92	Hydromorphone. Available at http://esc.syrres.com/interkow/webprop.exe .
C93	Hydromorphone. Clarke's Isolation and Identification of Drugs. 1986; 667-8.
C94	Hydromorphone. The Merck Index. 1989;(11 th ed.):762.
C95	Impax's Answer and Counterclaims in Civil Action No. 02 CV 2803 (SHS)
C96	Impax's Answer and Counterclaims in Civil Action No. 02 CV 7569 (SHS)
C97	Impax's Answer and Counterclaims in Civil Action No. 02 CV 8036 (SHS)
C98	IMS Study (D18).
C99	Inturrisi. Role of opioid analgesics. Am J Med. 1984 Sep 10;77(3A):27-37.
C100	Inturrisi. Management of cancer pain pharmacology and principles of management. Cancer. 1989 June;63:2308-20.
C101	Jamison et al. Survey of Opioid Use in Chronic Nonmalignant Pain Patients, 11 th ANNUAL SCIENTIFIC MEETING, AMERICAN PAIN SOCIETY, 1992 Oct. 22;Abstract #92467.

C102	July 31, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 80 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
C103	June 16, 2004 Reply Brief of Plaintiffs-Appellants in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs/Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaimant-Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant)</i> , United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1226, -1347, -1357.
C104	June 30, 2004 Reply Brief of Defendants/Cross-Appellants in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs/Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaimant-Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant)</i> , United States Court of Appeals for the Federal Circuit, Appeals Nos. 04-1189, -1347, -1357.
C105	Kaiko et al. A bioequivalence study of oral controlled-release morphine using naltrexone blockade. <i>J Clin Pharmacol.</i> 1995 May;35(5):499-504.
C106	Kaiko et al. A single-dose study of the effect of food ingestion and timing of dose administration on the pharmacokinetic profile of 30-mg sustained-release morphine sulfate tablets. <i>Current Ther Res.</i> 1990;47 (5):869-878.
C107	Kaiko et al. Analgesic onset And potency of oral controlled, release (CR) oxycodone and CR morphine. <i>Clinical Pharmacol & Ther.</i> 1996; Abstract 130 #PI-4.
C108	Kaiko et al. Basics of opioid analgesic pharmacodynamics. <i>J Pain Symptom Manage.</i> 1986 Spring;1(2):103-5.
C109	Kaiko et al. Bioequivalency of Controlled-Release 100 mg Morphine vs. Three Ms Contin 30 mg Tablets. 6 Proceedings of ASCO. 1987;271(Abstract 1066).
C110	Kaiko et al. Bioequivalency of controlled-release 60 mg morphine vs. two MS Contin 30 mg tablets. <i>Oncol Nurs. Forum. Suppl</i> 1987 Mar-Apr;Abstract #148P, 118.
C111	Kaiko et al. Controlled-release morphine bioavailability (MS Contin® Tablets) in the presence and absence of food. <i>HOSPICE J.</i> 1990;6(4) 17-30.
C112	Kaiko et al. Controlled-Release Oral Morphine (MS Contin Tablets, MSC) in Postoperative Pain. <i>Eur J Pharmacol.</i> 1990; 183 (6):1437-1438.
C113	Kaiko et al. Controlled-Release Oral morphine for Cancer-Related Pain: The European and North American Experiences, <i>ADVANCES IN PAIN RESEARCH AND THERAPY</i> , vol. 16 K.M. Foley, ed., Raven Press, Ltd., New York. 1990;171-89.
C114	Kaiko et al. Pharmacokinetic Characterization of Controlled-Release Oral Codeine for Chronic Cancer Pain. 5 Proceedings of ASCO 1986; 255 #996.
C115	Kaiko et al. Steady-state Bioavailability Evaluation of Controlled Release Oral Codeine, <i>FASEB J. ABSTRACT A 1558 #7333</i> May 1-May 5 Meeting of the Federation of American Societies for Experimental Biology (72nd Annual Meeting, Las Vegas NV) (1998).
C116	Kaiko et al. The Bioavailability of Morphine in Controlled-Release 30 mg Tablets per Rectum Compared With Immediate-Release 30-mg Rectal Suppositories and Controlled-Release 30-mg Oral Tablets. <i>Pharmacotherapy.</i> 1992;12 (2):107-113.
C117	Kaiko et al. The united states experience with oral controlled-release morphine (MS Contin Tablets): Parts I and II. Review of nine dose titration studies and clinical pharmacology of 15mg, 30-mg, 60-mg, and 100-mg tablet strengths in normal subjects. <i>Cancer.</i> 1989 June 1 Suppl.;63(11):2348-2354.
C118	Kaiko, Robert, Dr., Declaration dated 3/9/1993 in United States Patent Application No. 07/800,549, filed 11/27/1991.
C119	Kaiko. Clinical Protocol and Role of Controlled Release Morphine in the Surgical Patient. <i>Anesthesiol and Pain Manage.</i> 1991; 193-212.
C120	Kaiko. Relationship between opioid disposition and their pharmacological effects – an overview. <i>Postgrad. Med. J.</i> 1991; 67(SUPPL. 2):S44-9.
C121	Kaiko. The Pre- and Postoperative Use of Controlled-Release Morphine (MS Contin Tablets): A Review of the Published Literature” Medical Department, The Purdue Frederick Company, Royal Society of Medical Services, International Congress, Symposium Services. 1989;(No.149):147-160.
C122	Kalso et al. Hallucinations during morphine but not during oxycodone treatment. <i>Lancet.</i> 1988 Oct 15;2(8616):912.
C123	Kalso et al. Morphine and oxycodone hydrochloride in the management of cancer pain. <i>Clin Pharmacol Ther.</i> 1990 May;47(5):639-46.
C124	Kalso et al. Morphine and oxycodone hydrochloride in the management of cancer pain. <i>Clin Pharmacol Ther.</i> 1990 May;47(5):639-46.
C125	Kalso et al. Morphine and oxycodone in the management of cancer pain: plasma levels determined by chemical and radioreceptor assays. <i>Pharmacol Toxicol.</i> 1990 Oct;67(4):322-8.
C126	Kalso, et al. Intravenous morphine and oxycodone for pain after abdominal surgery. <i>Acta Anaesthesiologica Scandinavica.</i> 1991;35:642-646.
C127	Kaplan et al. Comparison of controlled-release and immediate-release oxycodone tablets in patients with cancer pain. <i>J Clin Oncol.</i> 1998 Oct;16(10):3230-7.
C128	Khan et al. Dissolution testing for sustained or controlled release oral dosage forms and correlation with in vivo data: challenges and opportunities. <i>International J., Of Pharmaceutics.</i> 1996;140:131-143.
C129	Khojasteh et al. Controlled-release oral morphine sulfate in the treatment of cancer pain with pharmacokinetic correlation. <i>J Clin Oncol.</i> 1987 Jun;5(6):956-61.

C130	Khojasteh et al. Safety, and Efficacy of Slow-Release Morphine Sulfate Tablets in Cancer Pain Therapy. 5 Proceedings of ASCO 256 Abstract #1000 (1986).
C131	Krant et al. Cancer Pain Management with Controlled-Release Oral Morphine. 5 Proceedings of ASCO. 1986;251(Abtract #981).
C132	Lapin et al. Guidelines for use of controlled-release oral morphine in cancer pain management. Correlation with clinical experience. Cancer Nurs. 1989 Aug;12(4):202-8.
C133	Lapin et al. Cancer pain management with a controlled-release oral morphine preparation. J Pain Symptom Manage. 1989 Sep;4(3):146-51.
C134	Lazarus et al. Absorption, testing, and clinical evaluation of oral prolonged-action drugs. J Pharm Sci. 1961 Sep;50:715-32.
C135	Lee et al. Methods to achieve sustained drug delivery. The physical approach: Oral and parenteral dosage forms. Sustained and Controlled Release Drug Delivery Systems. 1978;(3)123-204.
C136	Leeson. et al. The in vitro development of extended-release solid oral dosage forms. J Pharmacokinet Biopharm. 1985 Oct;13(5):493-514.
C137	Lehmann. Acrylic Latices from Redispersable Powders for Peroral and Transdermal Drug Formulations. Drug Dev And Industrial Pharm. 1956; 12(3):265-87.
C138	Leow et al. Comparative oxycodone pharmacokinetics in humans after intravenous, oral, and rectal administration. Ther Drug Monit. 1992 Dec;14(6):479-84.
C139	Leow et al. Single-dose and steady-state pharmacokinetics and pharmacodynamics of oxycodone in patients with cancer. Clin Pharmacol Ther. 1992 Nov;52(5):487-95.
C140	Leow. The clinical pharmacology of oxycodone. A thesis submitted for the degree of Doctor of Philosophy. The University of Queensland. 1993.
C141	Leslie et al. Controlled release morphine sulphate tablets--a study in normal volunteers. Br J Clin Pharmacol. 1980 May;9(5):531-4.
C142	Leslie. Continuous Controlled Release Preparations. Symposium Supplement Br J Clin Pharmacol. 1981;10:5-8.
C143	List of known opioids and known opiates.
C144	Lloyd et al. The efficacy and tolerability of controlled-release dihydrocodeine tablets and combination dextropropoxyphene/paracetamol tablets in patients with severe osteoarthritis of the hips. Cur Med Res Opin. 1992;13(1):37-48.
C145	LoRusso et al. Comparison of Controlled-release oxycodone-(OxyContin TM) tablets to controlled-release morphine (MS Contin [®]) in patients with cancer pain. American Pain Society. 15 th Annual Scientific Meeting. 1996;Abstract #675.
C146	LoRusso et al. The Effects of Oral Controlled-Release Morphine and Oxycodone on Cancer-Related Neuropathic Pain. American Pain Society: 17th Annual Scientific Meeting. 1998;Poster Abstracts 130 #724.
C147	MacDonald et al. A Double-Blind, Cross-Over Comparison Between Slow-Release Morphine (SRM) and Short-Acting Morphine (SAM) in the Treatment of Cancer Pain. 6 Proceedings of ASCO; 1987;44(Abtract #1054.
C148	Mandema et al. Pharmacokinetic Model For A New Oral Controlled Release Formulation Of Oxycodone. Anesthesiol. 1994;81(3A):A383.
C149	Maruta et al. Problems with the use of oxycodone compound in patients with chronic pain. Pain. 1981 Dec;11(3):389-96.
C150	May 12, 2004 Brief of Defendants/Cross-Appellants in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs/Counterclaim Defendants-Appellants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaimant- Cross Appellant), Endo Pharmaceuticals Holdings Inc. (Defendant-Cross Appellant)</i> , United States Court of Appeals for the Federal Circuit, Appeals Nos.04-1189, -1226, -1347, -1357.
C151	McKay. Pain management for urological malignancies. Urol Int. 1991;46(3):252-8.
C152	McTaggart et al. The evaluation of formulation and processing conditions of a melt granulation process. International J Pharmaceutics. 1984;19:139-48.
C153	Mikus. Polymorphic metabolism of opioid narcotic drugs: Possible clinical implications. Annals Acad. of Medicine. 1991 Jan;20(1):10-12.
C154	Morphine sulfate sustained release. Compendium of Pharmaceutical and Specialties. 1988;572-3.
C155	Morphine sulfate. Available at http://esc.syrres.com/interkow/webprop.exe .
C156	Morphine. Available at http://esc.syrres.com/interkow/webprop.exe .
C157	Morphine. Clarke's Isolation and Identification of Drugs. 1986;790-1.
C158	Morphine. The Merck Index. 1989;(11 th ed.):988-9.
C159	Mucci-LoRusso et al. Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study. Eur J Pain. 1998;2(3):239-49.
C160	Muhtadi et al. Codeine phosphate. Analytical Profiles of Drug Substances. 1981;(10):93-138.
C161	Muhtadi, Analytical profile of morphine. Analytical Profiles of Drug Substances. 1988;(17):259-366.
C162	Munday. Changes in Drug Release Rate 2, Effect of Temperature and Relative Humidity on Polymeric Film Coatings. 5th Cong. Int. Tech. Pharm. 1989; 2:55-60.

C163	Nichols et al. Oxycodone injection: Pharmacokinetics. Abstracts 10 th World Congress on Pain. 2002 Aug;59 (191-P87) and Final Study Report.
C164	November 8, 2001 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 160 mg, from Teva Pharmaceuticals USA to Purdue Pharma L.P.
C165	Oral oxycodone: new preparation. No better than oral morphine. rescrire Int. 2003 Jun;12(65):83-4.
C166	Oshlack. Internal memorandum regarding R&D. 1983 Aug.
C167	Oshlack. Notes on Example 2 of D1. The Purdue Frederick Research Center. 1982.
C168	Oxycodone HCl trihydrate. Compendium of Pharmaceuticals and Specialties. 1988;879.
C169	Oxycodone. Available at http://esc.syrres.com/interkow/webprop.exe
C170	Oxycodone. Clark's isolation of Drugs. 1986;841.
C171	Oxycodone. The Merck Index. 1989; (11 th ed.):1100.
C172	Parab et al. Pharmacokinetics of hydromorphone after intravenous, peroral and rectal administration to human subjects. Biopharm Drug Dispos. 1988 Mar-Apr;9(2):187-99.
C173	Paul et al. Pharmacological characterization of morphine-6 beta-glucuronide, a very potent morphine metabolite. J Pharmacol Exp Ther. 1989 Nov;251(2):477-83.
C174	Physicians Desk Reference 1994, 48th Edition, pages 1821-1824.
C175	Physician's Desk Reference, OxyContin, 56 Ed. at 2912-2916, (2002)
C176	Portenoy et al. Controversies in the long-term management of analgesic therapy in patients with advanced cancer. J Pain Symptom Manage. 1990 Oct;5(5):307-19.
C177	Portenoy et al. Oral controlled-release morphine sulfate. Analgesic efficacy and side effects of a 100-mg tablet in cancer pain patients. Cancer. 1989 Jun 1;63(11 Suppl):2284-8.
C178	Portenoy et al. The metabolite morphine-6-glucuronide contributes to the analgesia produced by morphine infusion in patients with pain and normal renal function. Clin Pharmacol Ther. 1992 Apr;51(4):422-31.
C179	Pöyhia et al. The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. Br J Clin Pharmacol. 1992 Jun;33(6):617-21.
C180	Pöyhia et al. The pharmacokinetics and metabolism of oxycodone after intramuscular and oral administration to healthy subjects. Br J Clin Pharmacol. 1992 Jun;33(6):617-21.
C181	Pöyhia et al. The pharmacokinetics of oxycodone after intravenous injection in adults. Br J Clin Pharmacol. 1991 Oct;32(4):516-8.
C182	Pöyhia et al., A review of oxycodone's clinical pharmacokinetics and pharmacodynamics. J Pain Symptom Manage. 1993 Feb;8(2):63-7.
C183	Product Information OxyContin (D17c).
C184	Product Information. 1990; 710-3 (D17a).
C185	Product Information. 2001 (D17b).
C186	Prosecution File History, U.S. Patent No. 4,861,598, filed July 18, 1986
C187	<i>Purdue Pharma, L.P., v. Endo Pharmaceuticals Inc.</i> , 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004).
C188	<i>Purdue Pharma, LP, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company(Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals Inc., (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant) v. EuroCeltique S.A. (Counterclaim Defendant)</i> 2004 WL 26523 (.S.D.N.Y. Jan. 5, 2004), 70 U.S.P.Q.2d 1185.
C189	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 01 CV 8507 (SHS).
C190	Purdue's Opening Brief After Trial dated 7/25/2003 in <i>Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A.</i> , 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C191	Purdue's Proposed Findings of Fact and Conclusions of Law After Trial dated 7/25/2003 in <i>Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A.</i> , 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C192	Purdue's Reply Brief After Trial dated 8/8/2003 in <i>Purdue Pharma L.P. et al. v. Endo Pharmaceuticals Inc. et al. v. Euroceltique S.A.</i> , 00 Civ.-8029 (SHS); 01 Civ.-2109 (SHS); and 01-Civ.-8117 (SHS).
C193	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 7569 (SHS).
C194	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 2803 (SHS).
C195	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company v. Impax Laboratories, Inc.</i> , Civil Action No. 02 CV 8036 (SHS).
C196	Purdue's Complaint in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 03 CV 2312 (SHS).
C197	Purdue's Complaint in <i>Purdue Pharma LP., The Purdue Frederick Company, the P.F. Laboratories, Inc., The Purdue Pharma Company v. Teva Pharmaceuticals USA, Inc.</i> , Civil Action No. 01 CV 11212 (SHS).

C198	Purdue's March 12, 2004 Opposition to Endo's Motion for Relief from Order with respect to Infringement in <i>Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) and EuroCeltique S.A. (Counterclaim Defendant) v. Endo Pharmaceuticals Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings Inc. (Defendant)</i> Civil Action Nos. 00-Civ 8029 (SHS); 01-Civ 2109 (SHS) and 01-Civ 8177(SHS).
C199	Purdue's Proposed Findings Of Fact And Conclusions Of Law After Trial in <i>Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company (Plaintiffs and Counterclaim Defendants) v. Endo Pharmaceuticals, Inc. (Defendant and Counterclaim Plaintiff), Endo Pharmaceuticals Holdings, Inc. (Defendant) v. EuroCeltique, S.A. (Counterclaim Defendant)</i> Civil Action Nos. 00-Civ. 8029 (SHS); 01-Civ. 2109 (SHS); Civil Action Nos. 01-Civ. 8117 (SHS).
C200	Purdue's Reply to Answer and Counterclaim in Civil Action No, 01 CV 8507 (SHS).
C201	Purdue's Reply to Answer and Counterclaims in Civil Action No. 03 CV 2312 (SHS).
C202	Reder et al. Ease of Titration to Stable Pain Control in Chronic Pain patients with Controlled-Release Oral Oxycodone (OxyContin™) Tablets, Abstracts, 8 th World Congress on Pain. Vancouver, Canada, 1996 August 17-22;53(Abstract #171).
C203	Reder et al. Physician Survey of Attitudes About Controlled-Release Oxycodone (OXYCR). AMERICAN PAIN SOCIETY, 14 th Annual Scientific Meeting; 1995 Nov 9-12;A144(Abstract #95878).
C204	Reder et al. Steady-state bioavailability of controlled-release oxycodone in normal subjects. Clin Ther. 1996 Jan-Feb;18(1):95-105.
C205	Renzi et al. Quantitative GLC determination of oxycodone in human plasma. J Pharm Sci. 1979 Jan;68(1):43-5.
C206	Riegelman et al. The application of statistical moment theory to the evaluation of in vivo dissolution time and absorption time. J Pharmacokinet Biopharm. 1980 Oct;8(5):509-34.
C207	Ripamonti. Traitement de la douleur et soins palliatifs pour les malades atteints de cancer avancé. Douleur et Analg. 1990;3:75-81 (in French, w/ English abstract).
C208	Risichitelli et al. Safety and efficacy of controlled-release oxycodone: a systematic literature review. Pharmacotherapy. 2002 Jul;22(7):898-904.
C209	Robinson et al. Theoretical approach to sustained-release multiple-dose therapy: noncumulative attainment of desired blood level. J Pharm Sci. 1970 Dec;59(12):1796-800.
C210	Robinson et al. Theoretical formulation of sustained-release dosage forms. J Pharm Sci. 1966 Nov;55(11):1254-63.
C211	Rodda. Sustained release preparations: estimation of plasma concentration in the one compartment open model when release is both immediate and zero order. Arch Int Pharmacodyn Ther. 1971 Dec;194(2):290-6.
C212	Rogers. The underutilization of oxycodone. J Pain Symptom Manage. 1991 Oct;6(7):452.
C213	Roy et al. Solubility and related physicochemical properties of narcotic analgesics. Pharm Res. 1988 Sep;5(9):580-6.
C214	Salzman et al. Can a controlled-release oral dose form of oxycodone be used as readily as an immediate-release form for the purpose of titrating to stable pain control? J Pain Symptom Manage. 1999 Oct;18(4):271-9.
C215	Savarese et al. Controlled-Release Oral Morphine Sulfate (MS Contin®), A Twelve Hour Analgesic Confirmed by Rescue Factor Design. 6 Proceedings of ASCO. 1987; Abstract #1038.
C216	Savarese et al. Steady-state pharmacokinetics of controlled release oral morphine sulphate in healthy subjects. Clin Pharmacokinet. 1986 Nov-Dec;11(6):505-10.
C217	Sawe et al. Morphine kinetics in cancer patients. Clin Pharmacol Ther. 1981 Nov;30(5):629-35.
C218	Schaefer et al. Melt granulation in a Laboratory scale high shear mixer. Drug Development and Industrial Pharmacy. 1990; 16(8):1249-77.
C219	Schneider. The pharmacology of oxycodone and morphine. A thesis submitted for the degree of Doctor of Philosophy. The University of Queensland. 1989.
C220	September 24, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 10 and 20 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company.
C221	September 4, 2002 Resubmission of August 19, 2002 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Impax Laboratories, Inc. to Purdue Pharma L.P. and The Purdue Frederick Company
C222	September 8, 2000 Paragraph IV Notice letter regarding Oxycodone Hydrochloride Extended-Release Tablets, 40 mg, from Endo Pharmaceuticals, Inc. to Euro-Celtique S.A., The Purdue Pharma Company, Purdue Pharma L.P., Steinberg & Raskin, Davidson & Davidson, The Purdue Frederick Company and The P.F. Laboratories, Inc.
C223	Silber et al. Utilizing pharmacokinetic principles in the design of controlled or sustained release formulations. Pharmacodynamics Dept., Med. Res. Div. Am. Cyanamid Co.;1-33.
C224	Slowey et al. Effect of premedication with controlled-release oral morphine on postoperative pain. A comparison with intramuscular morphine. Anaesthesia. 1985 May;40(5):438-40.
C225	Stambaugh et al. Double-blind, randomized comparison of the analgesic and pharmacokinetic profiles of controlled- and immediate-release oral oxycodone in cancer pain patients. J Clin Pharmacol. 2001 May;41(5):500-6.
C226	Steinbach et al. Evaluation of Pharmaceutical Availability from the Calculation of Drug Levels and Release Profiles. International J Pharm. 1980;4:327-335.
C227	Stelmach et al. Release of a drug from a dosage form. J Pharm Sci. 1965 Oct;54(10):1453-8.

	C228	Sun et al. A method of determining the in vivo drug release rate constant of sustained-release preparation. <i>Drug Metabolism And Disposition</i> . 1995;23 (4):449-454.
	C229	Sunshine et al. Analgesic Effects of Oral Oxycodone and Codeine in the Treatment of Patients with Postoperative, Postfracture, or Somatic Pain. 8 ADVANCES PAIN RESEARCH THERAPY, Foley, K.M. and Inturrisi, C.E. eds., Raven Press, New York; 1986;225-235.
	C230	Sunshine et al. Analgesic Efficacy of Controlled-Release Oxycodone vs. Immediate-Release Oxycodone , Alone and in Combination with Acetaminophen in Postoperative Pain: A Preliminary Study. <i>Problems of Drug Dependence</i> , 1992: Proceeding of the 54th Annual Scientific Meeting, U.S. Department of Health and Human Services. 1992;329.
	C231	Sunshine et al. Analgesic Efficacy of Controlled-Release Oxycodone in Postoperative Pain. <i>J. Clin Pharm</i> . 1996;36(7):595-603.
	C232	Sunshine et al. Analgesic oral efficacy of tramadol hydrochloride in postoperative pain. <i>Clin Pharmacol Ther</i> . 1992 Jun;740-746.
	C233	Sunshine et al. Controlled-Release Oxycodone vs. Immediate Release Oxycodone Alone and in Combination with Acetaminophen in the Treatment of Postoperative Pain. 11 th Annual Scientific Meeting, American Pain Society. 1992 Oct. 22;Abstract #92466.
	C234	Sunshine et al. Onset And Duration Of Analgesia For Controlled Release Vs. Immediate Release Oxycodone Alone And In Combination With Acetaminophen In Postoperative Pain. <i>Clin Pharm & Ther</i> . 1995;57 (2):137(Abstract #PI-7).
	C235	Sustained Release Medications, Noyes Data Corp., 1980; 3,4,10-15,96-99,335-337.
	C236	Teva's Answer and Counterclaims in Civil Action No. 01 CV 8507 (SHS).
	C237	Teva's Answer and Counterclaims in Civil Action No. 03 CV 2312 (SHS).
-	C238	Teva's Answer in Civil Action No. 01 CV 1121 2 (SHS).
	C239	The Merck Index, 11 th ed., Budavari, S. ed., at pages 384-385, 500, 762, 988, and 1100 (1989).
*	C240	Thirlwell et al. Pharmacokinetics and clinical efficacy of oral morphine solution and controlled-release morphine tablets in cancer patients. <i>Cancer</i> . 1989 Jun 1;63(11 Suppl):2275-83.
	C241	Thomas. Endone. Australia Prescription Products Guide. 1989;1(A-H):646.
	C242	Thomas. Endone. Australia Prescription Products Guide. 1990;1(A-H):676.
	C243	Thomsen et al. Prolonged Release Matrix Pellets Prepared by Melt Pelletization, Part IV: Drug Particles Size, and Binder Composition. <i>Pharmaceutical Technology Europa</i> . 1994 Oct; 19-24.
	C244	Thomsen et al. Prolonged Release Matrix Pellets Prepared by Melt Pelletization I. Process Variables. <i>Drug Dev and Ind Pharm</i> . 1993;19(15):1867-87.
	C245	Thomsen et al. Utilizing melt pelletization technique for the preparation of prolonged release products. Pelletization (material elaborated by assistant prof. Lars Juul Thomsen, Department of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technolgh," November 1992, 106 pages plus 3 appendices.
	C246	Urquhart. Performance requirements for controlled-release dosage forms: Therapeutic and pharmacological perspectives. <i>Controlled-Release Pharmaceuticals</i> . 1981;1-48.
	C247	Vallner et al. Pharmacokinetics and bioavailability of hydromorphone following intravenous and oral administration to human subjects. <i>J Clin Pharmacol</i> . 1981 Apr;21(4):152-6.
	C248	Wagner. BIOPHARMACEUTICS, Ch. 21: Quantitative Correlations of in Vivo Data with in Vitro Rate of Dissolution Data, 1 st ed., Drug Intelligence Publications, Illinois. 1971;140-7.
	C249	Wagner. Biopharmaceutics: 23: Rate of Dissolution In Vitro and In Vivo: Part VIII. Examples of Quantitative Correlations of in Vivo with in Vitro Data.. <i>Drug Intelligence And Clin Pharm</i> . 1970;4:232-9.
	C250	Walsh et al. Disposition of Oral Morphine in Advanced Cancer. 6 Proceedings of ASCO. 1987;270(Abstract #1063).
	C251	Welling et al. SUSTAINED AND CONTROLLED RELEASE DRUG DELIVERY SYSTEMS, Ch. 9: <i>Multiple Dosing of Sustained Release Systems</i> , J.R. Robinson, ed., Marcel Dekker, Inc., New York. 1978; 631-716.
	C252	Welling. PHARMACEUTICAL BIOEQUIVALENCE - Ch. 8 – <i>In Vitro Methods to Determine Bioavailability: In Vitro-In Vivo Correlations</i> , Marcel Dekker, Inc., New York. 1991;223-32.
	C253	Wiegand et al. Kinetics of plasma drug levels after sustained release dosage. <i>Biochem Pharmacol</i> . 1960 Jul;3:256-63.
	C254	Wilson et al. RATE CONTROL IN DRUG THERAPY, Ch. 4: Implications of Toxicology, Prescott. L.F. and Nimmo, W.S. eds., Churchill Livingstone, Edinburgh. 1985;30-37.
	C255	Wotherspoon et al. Analgesic efficacy of controlled-release dihydrocodeine. A comparison of 60, 90 and 120 mg tablets in cold-induced pain. <i>Anaesthesia</i> . 1991 Nov;46(11):915-7.
	C256	Yokokawa et al. Relationship between plasma concentration of morphine and analgesic effectiveness. <i>Postgrad Med J</i> . 1991;67 Suppl 2:S50-4.

EXAMINER

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